MAY - 2 2001

K010975

VARIAN
medical systems

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Premarket Notification [510(k)] Summary as required by 21 CFR 807.92

Date summary was prepared:

March 26, 2001

Submitter's Name:

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Contact Person:

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Device Name:

Eclipse 6.5

Classification Name:

Medical charged-particle radiation therapy system

Predicate Devices:

CadPlan v.6.0 Radiation Therapy Treatment Planning

Somavision v.6.0 Radiation Therapy Simulation Software System

Product Description:

The Varian Eclipse is a computer-based device used for calculating and displaying prospective or verification treatment plans for particular patient undergoing a course of radiation therapy. The system consists of a computer with graphics display, plotter output, film scanner and back lit digitizer input.

Intended Use:

The Varian Eclipse device is a treatment planning system used for diagnostic image analysis, contouring & segmentation, geometrical planning, photon and electron dose calculation and plan review.

Technological Characteristics:

See the attached "Specification Comparison Chart", Tab F

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Volume 2
ECLIPSE 6.5 USER MANUALS

The treatment planning process can be divided to several parts and Varian has written a separate manual for each purpose.

"**External Treatment Planning**" is the manual for the people (e.g. physicists, dosimetrists), who are responsible for creating and evaluating external treatment plans. This manual is also used with SomaVision (K992751).

"**Beam Configuration**" describes the general process of the beam configuration process. The beam configuration task is able to support variety of different kind of dose calculation algorithms (currently we support two). This manual will not necessarily change even if we added new algorithms later on* (see note below). The manual is written for physicists, who are responsible for dosimetry.

"**Preparing Images for Treatment Planning**" is a manual for medical doctors and the people who are responsible for importing the images, registering different image modalities and contouring of the images. This manual is used also with BrachyVision [K992762] and SomaVision [K992751].

"**IRREG Planning**" is a manual for the IRREG planning option. This module is optional. The IRREG planning is a different process from the normal external planning, thus it was necessary to create a separate manual.

"**Calculation Algorithms**" describes the current dose calculation algorithms, Single Pencil Beam for photons and Generalized Pencil Beam for electrons) and is written for physicists.

There are two major reasons why there are several manuals:

1. Modularity: Some of the manuals can be and are used for other Vision products (e.g. BrachyVision [K992762] and SomaVision [K992751]).

2. * Future plans: We have plans to develop new dose calculation algorithms and we have prepared the overall system so that the new algorithms can be added without any major rework of the software and the manuals. "Beam Configuration" module is the same for all kind of algorithms, thus we separated the algorithms to its' own manual. Later in the future when any new algorithm is ready, we can add new algorithm manuals without touching the beam configuration manual."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Linda S. Nash
Director, Regulatory Affairs and Quality Assurance
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K010975
Eclipse 6.5
Dated: March 30, 2001
Received: April 2, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010975

Device Name: ECLIPSE 6.5

Indications For Use:

The Varian Eclipse device is used to plan photon and electron radiation therapy treatments employing linear accelerators and other similar telepathy devices with x-ray energies from 1 – 50 MV, as well as Cobalt-60, and electron energies from 1 – 50 MeV. Eclipse will plan the 3D radiotherapy treatment approaches to combined modality plans, coplanar and non-coplanar fields static and ARC fields, beam modifiers, and beam intensity modulators.

Eclipse includes also tools for treatment preparation (diagnostic image analysis, contouring and segmentation) and plan review.

As part of the VARiS Vision System, Eclipse integrates the treatment planning in overall therapy process, while taking advantage of the Varian Vision database.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010975